

## PATENT APPLICATION TRANSMITTAL LETTER

Attorney's Docket No.

KNX1USA

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Submitted herewith for filing is the patent application of

Glen W. Knox

for OTOLOGIC PROSTHESES

Enclosed are:

- ( x ) Verified Statement Claiming Small Entity Status
- ( x ) Declaration and Power of Attorney
- ( x ) Two drawings
- ( )

For	No. Filed	No. Extra
Basic Fee		
Total Claims	10 - 20=	0
Indep Claims	1 - 3=	0
Multiple Dependent Claims Present		

Rate	Fee
	\$380
X09	
X39	
+130=	
Total:	\$380

C.F.R. 1.9 and 1.27

Rate	Fee
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X18=	
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X260=	
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Applicant or Patentee: Glen W. Knox Attorney's  
Serial or Patent No. : \_\_\_\_\_ Docket No.: KNX1USA  
Filed or Issued: Herewith  
For: OTOLOGIC PROSTHESES

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(F) AND 1.27(c)) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9 (c) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled Otologic Prostheses

☒ the specification filed herewith

☐ application serial no. \_\_\_\_\_, filed \_\_\_\_\_

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Glen W. Knox

NAME OF INVENTOR \_\_\_\_\_ NAME OF INVENTOR \_\_\_\_\_ NAME OF INVENTOR \_\_\_\_\_

Signature of Inventor \_\_\_\_\_ Signature of Inventor \_\_\_\_\_ Signature of Inventor \_\_\_\_\_

Date 1/11/99 \_\_\_\_\_ Date \_\_\_\_\_ Date \_\_\_\_\_

## OTOLOGIC PROSTHESES

### Field of the Invention

5 The present invention relates generally to otologic prostheses; and more particularly, to a novel and improved otologic prosthesis for relieving impaired conductive hearing of the middle ear.

### Background of the Invention

10 Otosclerosis is a common cause of progressive conductive hearing loss in which softening and hardening of minute areas of the ossicles (malleus, incus and stapes) in the middle ear produce abnormal bone growth and impede conduction of sound vibration from the eardrum to the inner ear. In about ten percent of patients with otosclerosis, the bone growth spreads to the stapes bone in particular, the final link in the middle ear chain. The stapes is a small stirrups-shaped bone with its base resting in a small groove, commonly called the oval window, in intimate contact with the inner ear fluids. When the amount of otosclerosis at this location is significant, as determined by careful hearing tests, a stapedectomy (or stapedotomy) is the treatment of choice.

25 A stapedectomy is a microsurgical technique in which all or a portion of the stapes is replaced by

a prosthesis. When the procedure was first introduced in the 1950s, many surgeons became skilled in the technique and while it is now performed by many more surgeons, on an average, there are relatively few performed per surgeon. Hence, proficiency is harder to maintain for the occasional stapes surgeon.

A stapedectomy is usually performed through an incision in the ear canal under local or general anesthesia. A flap consisting of canal skin and the tympanic membrane (eardrum) is elevated and the posterior superior bony external auditory canal is drilled away to expose the stapes, incus, and chorda tympani (facial nerve). The ossicles are palpated to confirm fixation of the stapes and mobility of the malleus and incus.

With care taken to preserve the chorda tympani, the joint between the incus and the stapes is separated with a knife, and a laser or other microsurgical instrument severs the stapes tendon and one crus (leg) of the stapes. The arch of the stapes bone may then be removed by fracturing off the other crus allowing the footplate to remain in the oval window. A laser is next employed to form a minuscule hole in the footplate for posting the stapedial prosthesis. In some cases, the footplate is also removed by a so-called "large hole"

technique and a vein grafted to the internal wall of the tympanum to cover the opening and to support the prosthesis.

5 After a hole is made in the footplate (or tissue is placed over the opening to the inner ear made after removing the footplate) one end of a biocompatible plastic or metal piston-like stapedial prosthesis of proper length is posted in the hole and the other end attached to the incus. A piece of fat or other tissue is taken, such as from a small incision behind the ear lobe, to seal any hole in the window, and the eardrum is folded back into its normal position with a small gelatin sponge to hold it in position.

10 A critical part of the procedure is attaching the prosthesis around the lenticular process of the incus due to its minuteness and delicate nature, typically about 3.5 mm to 6 mm long and 0.6 mm to 0.8 mm diameter, For instance, in U.S. Patent 20 5,370,689 to Causse one end of the prosthesis fabricated of PTFE is posted in a hole drilled in the exposed footplate and a split eyelet at the other end must be crimped around the incus. In U.S. Patent 3,714,869 to Shay Jr. one end of the 25 prosthesis is placed on a vein graft invaginated into the oval window, and a split eyelet at the other end must be forced open by elastic deformation

to fit onto the incus. Elastic recovery capacity of the eyelet causes it to restore to its original form in about 20 minutes and grip the incus firmly. U.S. Patent 3,838,468 to Armstrong discloses a stapedial prosthesis for use in cases where the footplate is also removed. A piston is fixed at one end to a vein graft for covering the oval window. A wire of stainless steel, platinum, gold or like biocompatible material shaped like a shepherd's crook extending from the other end, is crimped about the lenticular process of the incus. U.S. Patent 5,433,749 to Clifford et al. discloses a stapedial prosthesis of metal or plastic in which one end of a piston extends into the fluid in the inner ear and the other end is secured to the incus by a separate heat-shrinkable sleeve when heat is applied as by a laser.

It is readily apparent that great care and skill are required to secure these and similar prostheses to the lenticular process of the incus. The minute size of the prostheses also makes them extremely difficult to manipulate into proper position for tightening around the incus, even with state-of-the-art microsurgical instrumentation. Once in place, if the prosthesis is not tightened sufficiently about the incus, fluctuating hearing loss, dizziness, or extrusion of the prosthesis may

occur. If it is too tight, necrosis of the incus may occur. In either case, the tightening procedure in itself may cause trauma to the delicate middle ear structures, including fracture or subluxation (dislocation) of the incus.

Other otologic prostheses may be implanted by similar procedures directly between the malleus and the footplate of the stapes or the oval window of the inner ear.

#### Objects of the Invention

With the foregoing in mind, it is an object of the present invention to provide an otologic prosthesis which can be installed more easily with more confidence by the occasional ossicle replacement surgeon and with fewer complications and better hearing results.

Another object is to provide an otologic prosthesis which can be more readily connected to an ossicle with much less trauma to the delicate middle ear structures.

Still another object is to provide a stapedial prosthesis which is relatively simple in construction, utilizes state-of-the-art materials, and which can be more easily manipulated in the middle ear.

### Summary of the Invention

More specifically, these and other objects and advantages of the invention are accomplished by an otologic prosthesis of biocompatible shape memory alloy for conducting sound vibration from the eardrum, through the inner ear, to the oval window of the inner ear. One embodiment of the invention is a stapedial prosthesis including a shaft of nickel-titanium wire having means on one end portion for posting in a hole formed in the footplate of the stapes. The other end portion of the shaft, in a thermoelastic martensitic phase, is reversely turned to form a bight, as manufactured, to fit snugly around the lenticular process of the incus when installed. The bight is plastically deformable at ambient temperatures to fit loosely against the incus. When the wire temperature is elevated to a higher temperature, as by application of a laser beam, the bight returns to its memorized shape for positively embracing the incus. Preferably, a heat sink flange is mounted on the shaft for conducting heat to the bight when the laser energy is applied. Other embodiments of prostheses are disclosed.



### Brief Description of the Drawings

The foregoing and other objects, features and advantages of the present invention should become apparent from the following drawings, in which:

5           FIG. 1 is an enlarged, fragmentary, partially broken-away, perspective view of a human ear having one embodiment of an otologic prosthesis according to the present invention;

FIG. 2 is an enlarged perspective view of the otholithic prosthesis illustrated in FIG. 1;

FIGS. 3A-3D are perspective views of the prosthesis embodiment of FIG. 1, but showing it in various phases of installation on an incus process;

10           FIG. 4 is an elevational view another embodiment of an otologic prosthesis according to the present invention;

15           FIG. 5 is an elevational view of a further embodiment of otologic prosthesis according to the present invention; and

20           FIG. 6 is an elevational view of yet another embodiment of an otologic prosthesis according to the present invention.

### Description of the Preferred Embodiments

25           Referring now to the drawings, FIG. 1 illustrates a human ear having an outer ear structure OE, a middle ear structure ME, and an inner ear structure IE. The middle ear ME is

separated from the outer ear OE by the tympanic  
membrane T. The malleus M is connected to the  
tympanic membrane T, and the incus I is connected to  
the malleus. One embodiment of an otologic  
5 prosthesis 10 embodying the present invention is  
shown connecting the incus I to the oval window O  
adjacent the inner ear IE.

The otologic prosthesis 10 illustrated in FIG.  
1 is used in a so-called stapedectomy. When  
10 installed, the otologic prosthesis 10 provides a  
sound-conductive connection between a first otologic  
structure, such as the incus process I, and a second  
otologic structure, such as the oval window O. When  
installed as illustrated, vibrations from the incus  
15 process I are transmitted to the oval window O in  
the same manner as with a conventional prosthesis.

As discussed heretofore, a significant problem  
that exists with a conventional otologic prosthesis  
of the type described resides in the connection of  
20 the outer end of the prosthesis to the incus  
process. Presently, it is necessary to crimp the  
outer end of a wire-form prosthesis about the incus  
process, and because it requires great care, it is a  
difficult and time consuming portion of the overall  
25 stapedectomy procedure.

According to the present invention, the  
problems associated with prior art otologic

prostheses are overcome by the otologic prosthesis 10 which comprises an elongate shaft 11 of nickel-titanium metal wire alloy having biocompatible shape-memory properties, such as Nitinol. The shaft 11 has an upper, or outer, end portion 12 that is reversely turned on itself to form an open ended bight 13. As manufactured, the prosthesis 10 has an overall length of about 4mm, and the reversely turned bight has a radius of approximately 0.05mm. The diameter of the wire shaft is approximately .005 mm. The bight 13 is adapted to engage the incus process I as illustrated in FIG. 3D in the manner to be discussed.

The prosthesis shaft 11 has a lower, or inner, end portion 14 remote from the bight 13, and a fastening means as provided on this end portion for securing the shaft 11 to a second otologic structure, such as the oval window O shown in FIG. 3D. In the embodiment of FIG. 2 the fastening means includes a cylindrical piston 15 of plastic, such as polytetrafluoroethylene (PTFE) molded about the lower end of the shaft 11.

The bight 13 is opened by means of a tool to receive the incus process I and self-closes in response to heat to grip it. In order to accelerate the self closing action, a heat sink flange 20 is provided on the shaft 11 between the bight 13 and

the piston 15. In the illustrated embodiment, the heat sink flange 20 is provided by a flat metal plate which is preferably disposed in a plane transverse to the plane in which the bight 13 is formed, such as orthogonal to the plane of the bight 13. The heat sink flange 20 is secured to the shaft 11 as by welding. Thus, the heat sink flange 20 is disposed with its surface area readily exposed to the surgeon for receiving electromagnetic energy, such as may be applied by means of the laser beam customarily used in stapedectomys.

When struck by a laser beam, the heat sink flange 20 conducts heat upwardly along the shaft 11 to the bight 13 causing it to reversely turn on itself into its as manufactured condition for gripping the incus process as illustrated in FIG. 3D. The heat sink flange 20 is also large relative to the shaft 11 to provide a readily visible target for the surgeon to aim the laser beam.

Installation of the prosthesis 10 is straightforward. As best seen in FIG. 2A, the prosthesis 10 is shown in its normal, as manufactured, condition as described with respect to FIG. 2. After removal from the sterile package in the operating theater, the reversely turned bight 13 is straightened as illustrated in FIG. 3B. The prosthesis 10 is installed with its piston 15 engaged with the oval

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window 0, and the bight 13 is loosely engaged with the incus process as illustrated in FIG. 3C. Thereafter, the surgeon applies electromagnetic radiation by a laser to the heat sink flange 20 for heating the shaft 11 and causing the bight 13 to reversely turn on itself to its as manufactured shape and thereby firmly grip the incus process I. A temperature of approximately 86°F (30°C) is sufficient to cause the bight to reversely turn and engage the incus process I in short order. Thereafter, body temperature, being above the activation temperature, maintains the bight 13 in firm engagement with the incus process I.

FIG. 4 illustrates a second embodiment 110 of a prosthesis of the present invention. In the embodiment of FIG. 4, the piston is replaced with a circular loop 120 formed on the bottom of the shaft as in conventional wire prostheses.

In the embodiment of FIG. 5, a fastening means is provided by a reversely turned shaft end portion 215, much like the reversely turned upper end bight portion of the shaft illustrated in FIG. 2, but of a smaller radius. The reversely turned lower end portion in the FIG. 5 embodiment is in the same plane as the upper end bight and this embodiment is particularly suited for a malleus to stapes prosthesis.

In both the embodiments of FIG. 4 and FIG. 5, a heat sink flange 120 and 220 is provided for purposes as described above.

5 In a further embodiment, illustrated in FIG. 6, the shaft 311 is not of cylindrical wire construction. Rather, it is of a flat ribbon like construction providing upper and lower bights 313a and 313b lying in planes perpendicular to each other. An advantage of this construction is that the ribbon shaft 311 provides a continuous heat sink flange. This embodiment is particularly suited for use in providing an incus to stapes prosthesis.

10 In view of the foregoing, it should be apparent that the present invention now provides otologic prostheses which overcome many of the limitations of prior art prostheses by eliminating the need for crimping wire about an otologic structure and the concomitant disadvantages associated therewith.

15 While preferred embodiments of the present invention have been described in detail, various modifications, alterations and changes may be made without departing from the spirit and scope of the present invention as defined in the appended claims.

## CLAIMS

1. A self-securing otologic prosthesis,  
comprising:

a shaft formed of biocompatible shape-memory alloy,  
said shaft having a reversely-turned end portion forming a bight as manufactured, said bight being capable of being opened for receiving a first otologic structure and of closing into gripping engagement with said first otologic structure in response to heat, and  
fastening means on said shaft remote from said bight for operatively engaging a second otologic structure.

2. The self-securing otologic prosthesis according to claim 1 including a flange on said shaft providing a heat sink for enabling heat to be transferred by conduction to said bight after its engagement with said first otologic structure.

3. The self-securing otologic prosthesis according to claim 1 wherein said shaft is elongate and of small-diameter nickel-titanium metal alloy wire.

4. The self-securing otologic prosthesis according to claim 1 wherein said fastening means includes a piston.

5. The self-securing otologic prosthesis according to claim 4 wherein said piston has a circular end portion and is of a biocompatible plastic.

6. The self-securing otologic prosthesis according to claim 1 wherein said fastener means is provided by a closed loop formed integral with said shaft.

7. The self-securing otologic prosthesis according to claim 1 wherein said fastening means includes another bight of like construction to said first-mentioned bight but lying in a plane transverse to the plane of said first-mentioned bight.

8. The self-securing otologic prosthesis according to claim 1 wherein said shaft mounts a heat sink flange in a plane transverse to the plane of the bight for receiving electromagnetic radiation.



9. The self-securing otologic prosthesis according to claim 1 wherein said first otologic structure is an incus and said second otologic structure is an oval window.

10. The self-securing otologic prosthesis according to claim 1 wherein said first otologic structure is an incus and said second otologic structure is a stapes.

## OTOLOGIC PROSTHESES

### Abstract of the Disclosure

Otologic prostheses of shape-memory metal alloy self-secure about an otologic structure when heat is applied to a preformed bight by means of a laser.

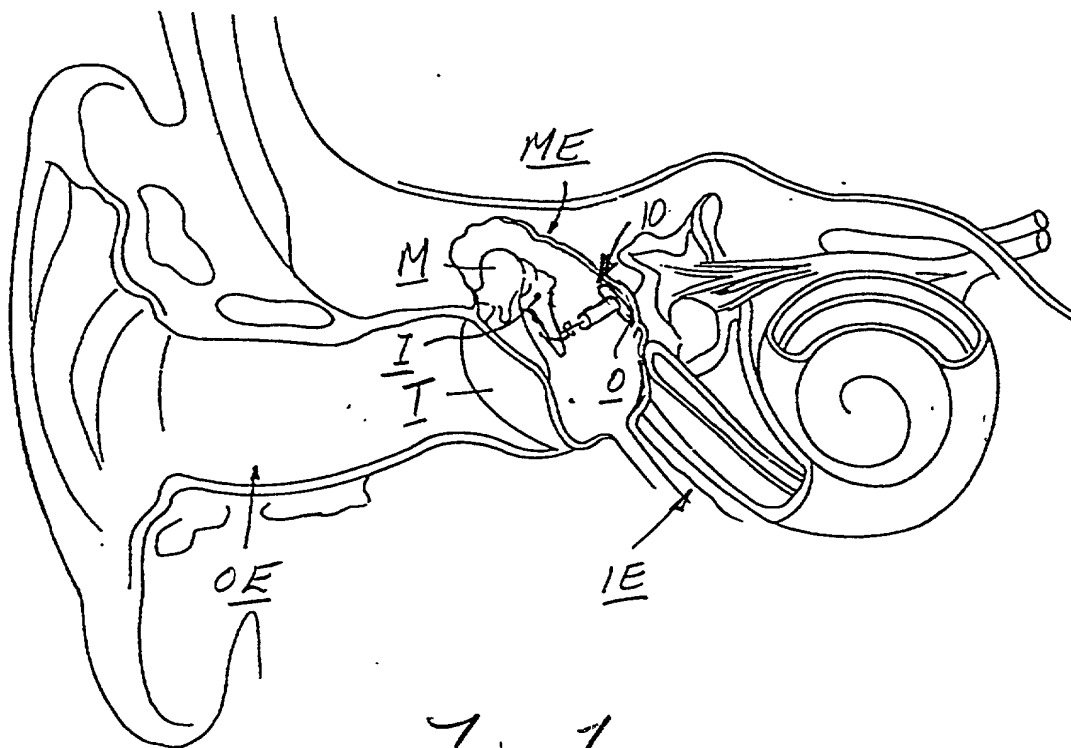


Fig. 1

FIG. 2 is a perspective view of the device 10 in a first position. FIG. 3A and FIG. 3B are perspective views of the device 10 in a second position. FIG. 3C and FIG. 3D are perspective views of the device 10 in a third position. FIG. 4 is a perspective view of the device 110 in a first position. FIG. 5 is a perspective view of the device 210 in a first position. FIG. 6 is a perspective view of the device 310 in a first position.

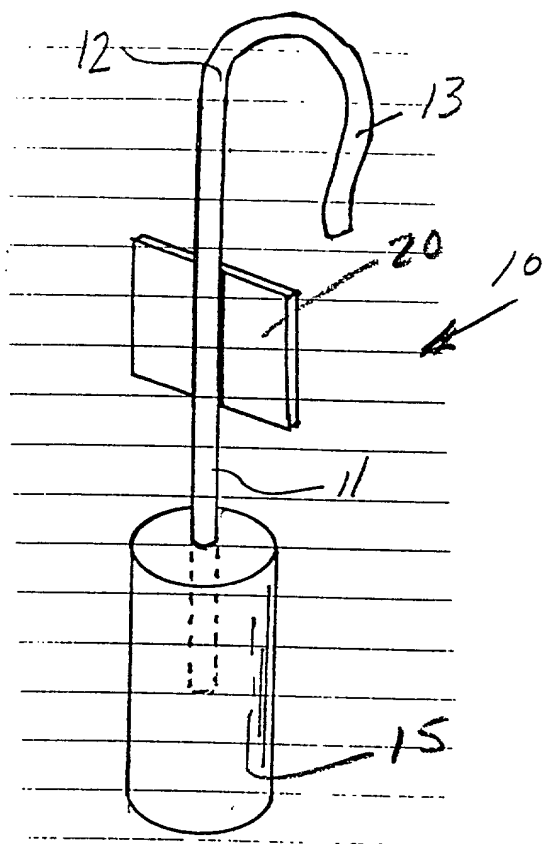


Fig. 2

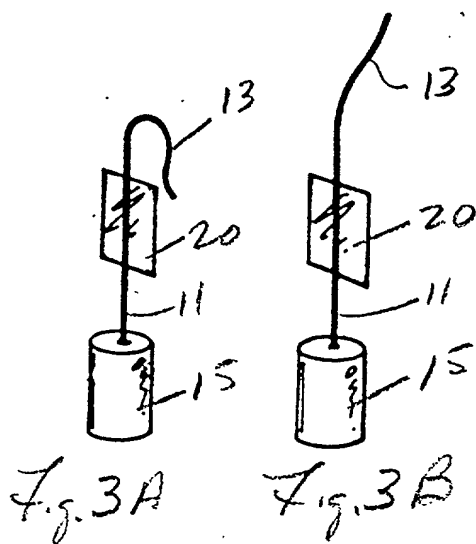


Fig. 3A

Fig. 3B

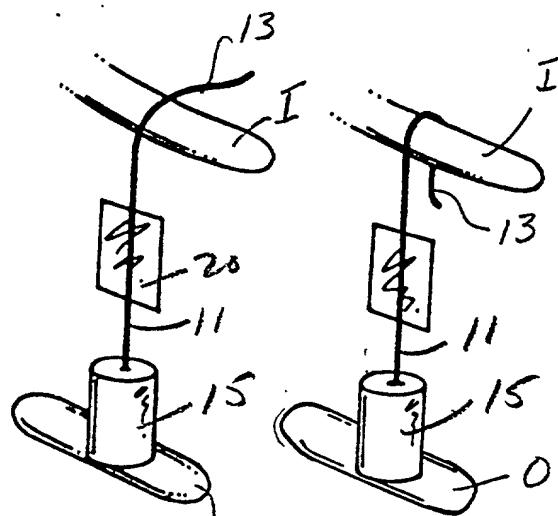


Fig. 3C

Fig. 3D

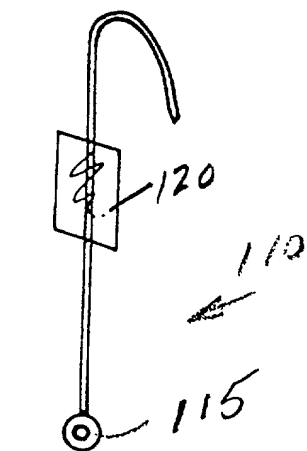


Fig. 4

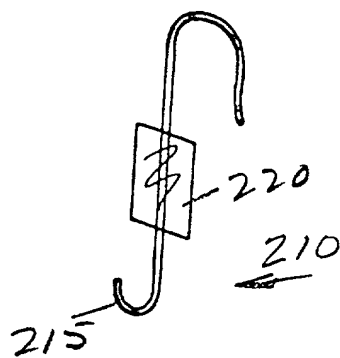


Fig. 5

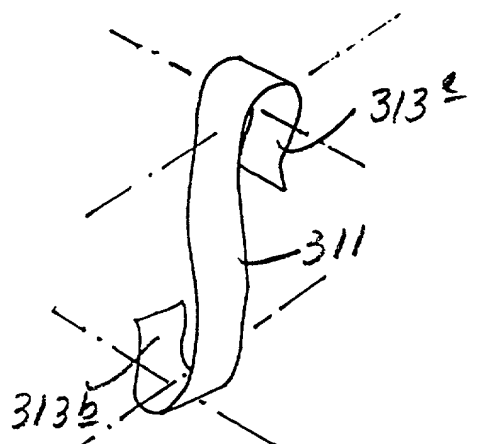


Fig. 6

[illegible]

My residence, post office address and citizenship are as stated below next to my name,

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information known

to me to be material to patentability, as defined in Title 37, Code of Federal Regulations, Section 1.56, which became available between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.) (Filing Date) (Status - patented,  
pending, abandoned)

I hereby appoint the following attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: STANLEY B. KITA, Registration No. 24,561; GEORGE A. SMITH, JR., Registration No. 24,442; WILSON OBERDORFER, Registration No. 17,379; MARY E. BAK, Registration No. 31,215; HENRY HANSEN, Registration No. 19,612, CATHY A. KODROFF, Registration Number 33,980, WILLIAM BAK, Registration Number 37,277.

Address all telephone calls to \_\_\_\_\_ at telephone no. (215) 540-920 . Address all correspondence to HOWSON AND HOWSON, Spring House Corporate Center, P. O. Box 457, Spring House, Pennsylvania 19477.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor: Glenn W. Knox

Inventor's signature



1/11/99  
Date

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